

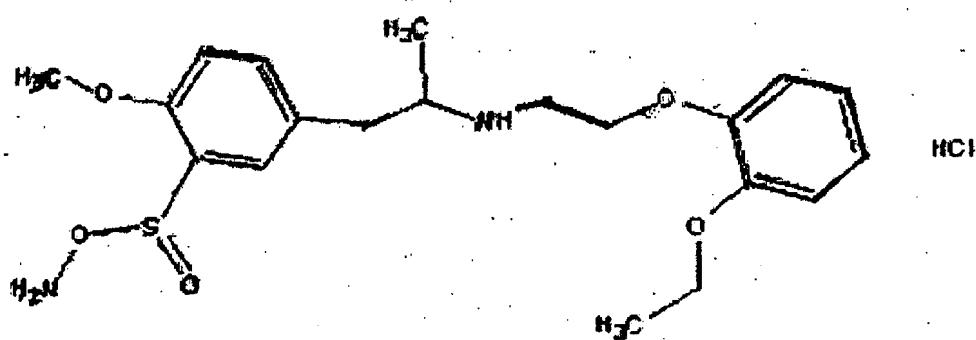
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IN THE SPECIFICATION

Please amend the specification as follows:

Please replace the figure at the top of Page 2 with the following more legible version of the figure:



Please replace the first paragraph (paragraph [9]), on page 3, with the following amended paragraph:

-- As an oral controlled-release tamsulosin HCl formulation, Harnal[?]® capsule (sold from Yamanouchi Pharmaceutical Co., Ltd.) is prepared by the above prior method comprising: mixing tamsulosin HCl with crystalline cellulose; adding an aqueous emulsion of methacrylic acid copolymer to the mixture; granulating and drying the resulting mixture; spraying and coating the granules with an aqueous solution of methacrylic acid copolymer; drying and sieving the coated granules. This prior method is being actually applied for the preparation of tamsulosin HCl sustained-release formulations. Here, the crystalline cellulose acts as not only an excipient to

give a given bulkness, but also a release-controlling agent which helps the sustained release of tamsulosin HCl while maintaining the structure and strength of granules with methacrylic acid copolymer, by virtue of its poor water solubility. However, in this prior method, if other general excipients (e.g., lactose and starch) than the crystalline cellulose are used together in the preparation of granules other than a final formulation, the release of tamsulosin HCl will be increased rapidly with the general excipients due to an accelerated increase in water infiltration with time, resulting in a rapid decrease in the physical strength of the granules. This makes the sustained release of tamsulosin HCl difficult. - -

On page 4, after paragraph [14] delete the first occurrence of the heading [Disclosure of Invention].

Please replace the fifth full paragraph (paragraph [37]), which spans from pg. 6 to pg. 7, with the following amended paragraph:

-- Glyceryl dibehenate and hydroxypropylmethylcellulose, which can be used in the present invention, are added for the preparation of a sustained-release tablet. Glyceryl dibehenate is hydrophobic in nature, so that it forms the interface between tamsulosin HCl and juice regardless of the kind of juice, to make the dissolution rate of the active ingredient slow. Glyceryl dibehenate is commercially available under the

trademark of, for example, Compretol 888 ATO [?]®. It is used at the amount of 10-200 parts by weight, preferably 25-150 parts by weight, and more preferably 50-100 parts by weight. Moreover, hydroxypropylmethylcellulose hydroxypropylmethylcellulose has the property of cellulose polymers. Namely, it shows intrinsic viscosity in an aqueous solution and is wetted and swollen in an aqueous solution. Due to such a property, it acts to prevent the rapid disintegration of a solid dispersion tablet to maintain the tablet form in gastrointestinal fluid and dissolution fluid for a sufficient time, thereby maintaining the surface area of the tablet at a constant level. Accordingly, hydroxypropylmethylcellulose hydroxypropylmethylcellulose acts to ensure the sustained dissolution pattern of the tablets for an extended period of time and to reduce the deviation between the tablets. It is commercially available under the trademark of, for example, Metolose 60SH4000[?]®. It is used at the amount of 10-300 parts by weight, and preferably 25-200 parts by weight, relative to one part of tamsulosin HCl. --

Please replace the first full paragraph on page 7 (paragraph [28]) with the following amended paragraph:

-- In the inventive preparation method, additives that are conventionally used in the preparation of a sustained-release tablet may be used. Examples of the additives include excipients such as lactose, corn starch, cellulose polymer (e. g.,

hydroxypropylmethylcellulose hydroxypropylmethylcellulose, such as Metolose[?]® 60SH-4000 or Metolose[?]® 60SH-50, sold from ShinEtsu Co., Japan; hydroxypropylcellulose, a modified cellulose as a hydrophilic polymer, such as HPC-L[?]® sold from ShinEtsu Co., Japan; and hydroxypropylcellulose phthalate, such as HPMCP[?]® sold from ShinEtsu Co., Japan), mannitol, laolin, starch, powdered white sugar, and calcium phosphate, and lubricants, such as magnesium stearate, talc, calcium stearate, and fumed silicon dioxide. Preferred examples of the excipients include but are not limited to lactose, corn starch and cellulose polymer, and the preferred example of the lubricant includes but is not limited to magnesium stearate. --

On page 9, after paragraph [44] and before paragraph [45], please change "Description of Drawings" to -- Brief Description of Drawings --.

On page 9, please replace the third full paragraph (paragraph [47]) with the following amended paragraph:

-- FIG. 3 is a graphic diagram showing the average dissolution rate of tamsulosin HCl with time for the tamsulosin HCl tablet prepared in Example 4 of the present invention and for the prior tamsulosin HCl sustained-release capsule (Harnal [?]® capsule; sold from Yamanouchi Pharmaceutical Co., Ltd.) using coated granules as a control, in which the dissolution rate was measured in a dissolution test under

simulated human gastrointestinal conditions. --

On page 12, please replace the last paragraph (paragraph [121]) with the following amended paragraph:

-- Preparation of test solution [121] The test was conducted according to the dissolution test method 2 described in Korea Pharmacopeia. For the preparation of a test solution, 1 ml of a polysorbate 80 solution (3[?]→200) was added to 500 ml of a first solution described in a disintegration test method. At 2 hours after the initiation of dissolution test, the test solution was replaced with 500 ml of phosphate buffer solution (37 ± 0. 5°C; pH 7.2). --

On page 13, please replace paragraph [125] with the following amended paragraph:

-- Column: Capelle Pak[?]® 3 mm x 150 mm, 5µm C₁₈ (ODS).--

On page 14, please replace the first paragraph (paragraph [139]), with the following:

-- The sustained-release tablet containing 0.2 mg of tamsulosin HCl prepared

in Example 4 was used as the test sample of the invention, and a prior tamsulosin HCl capsule (Harnal[?]® capsule, sold from Yamanouchi Pharmaceutical Co., Ltd.) was used as a control. The tablet and the capsule were subjected to a dissolution test under simulated human gastrointestinal conditions in the same manner as in Test Example 1 above. --

On page 14, please replace paragraph [141] with the following:

-- The results of the dissolution test under simulated human gastrointestinal conditions are shown in FIG. 3. In FIG. 3, the symbols-O-and-●-represent the test results for the tablet prepared in Example 4, and the prior capsule (Harnal [?]® capsule), respectively. As evident from the test results, the tamsulosin HCl tablet according to the present invention showed substantially the same dissolution pattern as that of the prior tamsulosin HCl capsule. --

On page 14, please replace paragraph [143] with the following:

-- The tablet containing 0.2 mg of tamsulosin HCl prepared in Example 4 was used as the test sample of the invention, and the prior tamsulosin HCl capsule (Harnal [?]® capsule, sold from Yamanouchi Pharmaceutical Co., Ltd.) containing 0.2 mg of tamsulosin HCl was used as a control. Each of the tablet and the capsule was

administered orally to 32 healthy adult male volunteers in 2 x 2 crossover trial. Then, the drug concentration in blood with time for each volunteer was measured. --

Please replace the paragraph spanning pages 14 and 15 (paragraph [145]), with the following amended paragraph:

-- The average blood drug concentrations with time, which had been measured after administering the inventive sample and the control to 32 volunteers, are shown in FIG. 4. In FIG. 4, the symbols-O-and-●-represent the average blood concentration of tamsulation HCl with time for the tablet prepared in Example 4, and the prior capsule (Harnal [?]® capsule), respectively. --